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09/830,176	04/23/2001	Joseph P. Dougherty	13257-00040	2969

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,176

Applicant(s)

DOUGHERTY ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 8 is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application is 371 national stage filing of PCT/US99/25477, filed October 29, 1999, which claims benefit to provisional application 60/106,533, filed October 31, 1998.

Applicants' amendment filed March 2, 2005, has been received and entered. The Abstract has been added. The specification has been amended. Claims 1, 2, 7 have been amended. Claims 4-6 and 9-19 have been cancelled. Claims 1-3, 7 and 8 are pending.

Election/Restrictions

Applicant's election of Group I, was acknowledged. The election was treated as an election without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, (MPEP § 818.03(a)). No new arguments are presented, and claims 4-6 and 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions have been canceled.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-3, 7 and 8 are under examination as they are drawn to the elected invention of a composition comprising transduced myeloid committed stem cells and a method of use to express an exogenous nucleic acid sequence.

Specification

The disclosure objected to because it did not contain an abstract and that it contains sequences that have not been identified with specific SEQ ID NO sequence identifiers is withdrawn.

The addition of an abstract and the amendment to the specification have obviated the objections.

Priority

The amendment to the specification has addressed the issue regarding priority.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1 and 2 have been amended to recite “spleen-derived” and the metes and bounds of what is meant by derived is considered indefinite because how similar or different from any other cell obtained by a different means or source is not clearly set forth in the claim nor the specification. It is noted that the specification teaches that myeloid-committed stem cells can be obtained from a spleen, but this fails to establish the

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implied process of spleen to derive a cell, or what other methods are contemplated and what cells result in a process of derivation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 (and dependent claim 3) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In this case, the amendment and recitation of "spleen-derived" is considered new matter. Applicants do not point to any specific portion of the specification for support of the amendment. Review of the specification provides support for the fact that stem cells can be obtained from the spleen, however at the same time it also supports that they can be obtained from other sources such as bone marrow (page 2, lines 5-10). To this end, claims 7 and 8 are not included because they are supported by the instant disclosure. However, with respect to claims 1-3, the term "spleen-derived" has no literal support, nor is there figurative support to establish how the claimed cell can or would be distinguished. Further, the term "derived" encompasses more than simply obtaining, and the specification fails to provide for methodology beyond the simple isolation of a cell from a spleen. Additionally, the specification fails to provide the

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necessary description of the such a cell that would allow the artisan to clearly establish the claims cell from other cells obtained from other tissue sources or by other means.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. As discussed above, the present specification provides for the isolation of a pluripotent cell from the spleen, however fails to provide any other methodology or a detailed characterization of the claimed cell.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz DL *et al.* (Exp Hematol. 1994 Aug;22(9):857-65).

Applicants summarize the basis of the rejection (page 8) and argue that the M1 cell taught by Freas-Lutz *et al.* is a bone marrow derived cell line which fails to meet the limitations of the amended claims (page 9). See Applicants' amendment, bridging pages 8-9. Applicants arguments have been fully considered, and found persuasive in part.

Initially, Examiner would agree that the art supports the fact that the M1 cell is bone marrow derived, the methods of claim 7 and 8 are no longer anticipated. However, with respect to the product claims the amendment to recite "spleen derived" fails to differentiate the claimed cell from that taught by Freas-Lutz *et al.* There is nothing in the claim nor the specification that provides for more than the functional limitation that the myeloid committed stem cell is capable of differentiating into myeloid lineages. In this case, cells from the bone marrow meet this functional requirement. As noted previously, Freas-Lutz *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase into the isolated cells. Further, the various retroviral constructs taught have various promoters to analyze the expression and activity of glucocerebrosidase, including the

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use of the phosphoglycerate gene promoter which is expressed in macrophages (a differentiated myeloid cell). Since the instant specification does not specifically define what a myeloid committed stem cell is, and in the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Migita *et al.* (PNAS 92:12075-12079).

Applicants summarize the basis of the rejection and argue as above in traverse of the teachings of Freas-Lutz *et al.* the cells of Migita *et al.* fail to meet the limitations of the claimed invention. See Applicants' amendment, bridging pages 9-10. Applicants arguments have been fully considered, but not found persuasive.

Initially, Examiner would agree that Migita *et al.* do not specifically teach to obtain the cell from the spleen nor that the human CD34+ cell was not obtained from the spleen, therefore the method of claim 7 and 8 is no longer anticipated. However, as reasoned above, the product claims the amendment to recite "spleen derived" fails to differentiate the claimed cell from that taught by Migita *et al.* There is nothing in the claim nor the specification that provides for more than the functional limitation that the myeloid committed stem cell is capable of differentiating into myeloid lineages. In this case, cells from the bone marrow meet this functional requirement. As noted in the prior office action, Migita *et al.* teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase. One of the cell types used by Migita *et al.* are human CD34+ cells (see top of page 12078, for example) which represent a population of cells which have the capacity to differentiate into

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various cells of the myeloid lineage. As discussed above, the instant specification does not specifically define what a myeloid committed stem cell is, and is being given the broadest reasonable interpretation of being any cell with a restricted ability to become a differentiated cell of the myeloid lineage. The CD34+ cells taught by Migita *et al.* meet this interpretation of a myeloid committed progenitor cell because it is capable of myeloid specific differentiation.

Conclusion

Claims 7 and 8 are allowed. While myeloid committed cells were known to be present in the spleen as early as 1982 in the prior art (see Magli *et al.* Nature, 1982), they represented a non-renewable and short lived source of such a cell type as summarized in the instant specification (age 2, lines 25-33). There is insufficient motivation in the art of record to use the spleen as a source of myeloid committed stem cells in methods of expressing myeloid specific proteins. The present invention is based in part on the observation and the first to describe that the spleen also contains a longer lived committed stem cell.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


AUG 32